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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,880	09/28/2000	George B. Stefano	09598/004001	6475

7590 12/04/2001

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EXAMINER	
LANDSMAN, ROBERT	
ART UNIT	PAPER NUMBER
1647	12

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,880	STEFANO ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 33-40* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

1. Election/Restriction

A. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claim(s) 1-16, drawn to a method for screening for modulators of a mu3 opioid receptor.

II. Group II, claim(s) 33-40, drawn to a method for screening for modulators of an estrogen surface receptor.

B. The inventions are distinct, each from each other because of the following reasons:

Inventions I and II are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

C. A telephone call was made to J. Patrick Finn III on March 08, 2001 to request an oral election to the above restriction. Applicant's election of Group II, claims 33-40, is acknowledged with traverse.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

2. Title

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods for identifying estrogen surface receptor agonists.

3. Abstract

A. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

4. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 33-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 33 recites a method for identifying an estrogen surface receptor agonist by contacting a cell with a test molecule and determining if said test molecule induces an estrogen surface receptor-mediated response. While Applicants do provide examples in the specification of how to detect ESR activities, such as NO and Ca^{2+} release, Applicants have not taught the artisan how to determine that the test molecule is acting specifically via an ESR among all the various types of endogenously expressed receptors in that cell, such as opioid receptors, which also affect NO and Ca^{2+} release. There is no guidance or working examples of how the artisan would be able to identify which specific receptor was binding, and being activated by, the test molecule, nor would it be predictable to the artisan how to determine the exact receptor being bound and activated by the ligand. The specification does mention that antagonists, or

NOS inhibitors, can be used. However, this does not identify the specific receptor affected by the test molecule, only that a particular family, or, at most, subfamily, of receptor is being activated since it is likely that various receptors and other proteins in a cell would activate the same or similar pathways as does an ESR, especially in the absence of any functional limitations (i.e. what constitutes a specific ESR activity).

Therefore, in summary, due to the lack of guidance of how the artisan would be able to identify which specific receptor was binding, and being activated by, the test molecule, as well as the lack of predictability to one of ordinary skill in the art how to determine the exact receptor being bound and activated by the ligand, the Examiner holds that undue experimentation would be necessary to practice the invention as claimed.

Furthermore, even if Applicants were enabled for the claimed method of identifying ESR agonists, they would not be enabled for a method of identifying agonists in all species. Applicants have only disclosed these methods using human tissue (page 42, lines 7-23 of the specification). Therefore, the claims should be limited to the use of these methods for screening agonist for human ESRs only.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 33-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the recitation of proper controls to identify that the test molecule act specifically

through ESRs as well as how these detection steps are to be performed and how the results are to be interpreted. For example, the recitation of "monitoring nitric oxide synthase activity" is vague. The claim does not recite what steps are involved in measuring this activity, nor what an increase or decrease in this activity indicates.

B. Claims 33-40 are also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims are incomplete because cells may comprise more than one type of ESR and Applicants do not teach sufficient steps to determine which ESR the test compound is binding to and activating. Even in claim 36, for example, which recites that the receptor is ESR1, it is still unclear how Applicants would be able to determine this was the receptor being activated by the test compound. Similarly, as taught on page 2, line 24 of the specification, compounds such as tamoxifen can interact with the nuclear estrogen receptor, which can also affect ESR1 (page 3, line 13).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 03, 2001

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600